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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,040	11/20/2006	Juswinder Singh	14937.0011	4856
27890	7590	07/21/2008	EXAMINER	
STEPTOE & JOHNSON LLP			BORIN, MICHAEL L	
1330 CONNECTICUT AVENUE, N.W.				
WASHINGTON, DC 20036			ART UNIT	PAPER NUMBER
			1631	
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			07/21/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/580,040	SINGH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 17 April 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-32,41-54 and 68-73 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-32,41-54,68-73 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

    1. Certified copies of the priority documents have been received.

    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
    Paper No(s)/Mail Date 05/09/2008.

4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_ .

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

**06/2008**

**DETAILED ACTION**

**Status of Claims**

Response to restriction requirement filed 04/17/2008 is acknowledged. Applicant elected, without traverse, Group I. Claims 33-40 and 55-67 are canceled.

Claims 1-32,41-54,68-73 are pending.

***Information Disclosure Statement***

Applicants' Information Disclosure Statement filed 05/09/2008 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

***Claim Objections***

Claims 70-73 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 68 is limited to describing protein sequence of one protein ("a first protein") by a disulfide signature, whereas claims 70-73 address another , "a second" protein.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4,7, 9-16, 17-22,24-32, 41-43, 45,47-54 are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble in base claims 1,17,41 states that the method is for “detecting similarity” between protein sequences ; yet, there is no method step that results in detecting such similarity. Merely comparing protein sequence characteristics which may or may not be similar does not result in detecting similarity. The claims do not set forth the conditions/state when the method identifies the similarity. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

***Claim Rejections - 35 U.S.C. § 101***

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

4. Claims 1-32,41-54,68-73 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a computational process of detecting protein sequence similarity.

A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be “useful,” the claim must produce a result that is specific, substantial, and credible. For a claim to be “tangible,” the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be “concrete,” the process must have a result that can be substantially repeatable or the process must substantially produce the same

result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself.

The instant claims do not include any tangible result. A tangible requirement requires that the claim must set forth a practical application of the computational steps to produce a real-world result. No practical result is recited in the claims; thus the instant claims do not include any tangible result.

Furthermore, in regard to claims 17, 41, and claims dependent therefrom, “Computer-Related Inventions” section of the MPEP at section 2106, Part IV, subpart B, also clarifies that claiming such non-statutory subject matter on a computer medium or in software does not prevent this rejection.

### ***Claim Rejections - 35 USC § 102 and 103.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2,5,7,17,18,41,68-72 are rejected under 35 U.S.C. 102(a) as anticipated by Benham et al (Protein Sci. 1993 2: 41-54).

Benham teaches comparing proteins using disulfide bond patterns. disulfide bond patterns in Benham are viewed as “disulfide signature”. A number of nmeasures of similarity based on the disulfide boind patterns is suggestede (see p. 44-46). The databases of National Biomedical Research Foundation protein sequence and Brookhaven National Laboratories protein structure (PDB) are examined, and the occurrences and character of disulfide bonding patterns in them are determined. The PDB structure database is examined to determine the extrinsic topologies of polypeptides containing disulfide bonds. See Abstract. The method is viewed as comparison of protein “disulfide signatures”.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above, and that the above described referenced method and related computer implemented software applications directly anticipates the methods of detecting similarity between protein sequences comprising a plurality of disulfide signatures and domains as instantly claimed as well as the corresponding program and computer readable media.

Claims 1-2,5,7,17,18,41,68-72 are rejected under 35 U.S.C. 102(b) as anticipated by Mas et al (see IDS)

Mas et al teaches comparing protein sequences by means of their disulphide bridge topology, i.e., the order in which cysteine residues are connected. The sequences are superimposed by disulfide bridge topology. Mas et al. set forth methods and related computer applications for analyzing relationship between proteins using structural superposition (see Abstract). Mas et al. further disclose a new program and approach (KNOT-MATCH) developed for automated structural superpositioning of proteins by means of disulphide bridge topology. Superposition by disulphide-bridge topology allows to find structural similarities not only between clearly related proteins, but also between proteins apparently not related by sequence or in function.

Claims 1-4,7,13,17-20,29,41-43,46,52,68-72 are rejected under 35 U.S.C. 102(a) as anticipated by Chuang et al (see IDS)

Chuang et al teach describing disulfide bonding patterns in protein. The description of disulfide bonding includes cysteine spacing (p. 1, last paragraph) and cysteine topology (p. 2, top paragraph and Fig. 1. Disulfide chains are classified hierarchically in three levels: disulfide-bonding numbers, disulfide-bonding connectivity, and disulfide-bonding patterns. p. 2 , section “Data Sets” and Fig.1. Chuang teaches comparing disulfide patterns in proteins which reads on detecting similarity between protein sequences (e.g., as in claims 1, 17, 71). Further, the reference teaches

clustering database proteins based on their “disulfide signature” . p. 2, last paragraph through p. 3, Fig.7.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above, and that the above described referenced method and related computer implemented software applications directly anticipates the methods of detecting similarity between protein sequences comprising a plurality of disulfide signatures and domains as instantly claimed as well as the corresponding program and computer readable media.

Claims 5,6,8-12,14-16, 25-28, 30-32, 44,45,47-51,53,54 are rejected under 35 U.S.C.103(a) as unpatentable over Chuang et al

With respect to claims 5,6,8-12,14-16, and corresponding claims 25-28, 30-32, and 44,45,47-51,53,54, if there are any differences between Applicant's claimed method and that of the prior art, the differences would appear minor in nature. Although the prior art do not teach all the aspects of using disulfide signatures as claimed, the nature of the problem to be solved – comparing protein sequences using disulfide connection characteristics - would lead inventors to look at references relating to computational methods of sequence comparison. Based on particular situation, it would be conventional and within the skill of the art to make decision to use of simplified, rather

than full “signature” (as in claims 9,10) and/or to select or determine such result-oriented variables as parameters or criteria to be used as a measure of similarity of “disulfide signatures” (as in claims 5,6,8), or appropriate criteria for clustering database sequences (as in claims 14-16), or, or associating disulfide signatures with other identifiers (as in claims 11,12)

The method does not address using “the number of residues between a pair of cysteines joined by a disulfide bridge” or “the number of residues between the first cysteine of each disulfide bridge and the first cysteine of the next” as addressed in the instant claims (claim 3, for example). However, for a known sequence, having known the order in which cysteine residues are connected inherently provides the knowledge of both using “the number of residues between a pair of cysteines joined by a disulfide bridge” or “the number of residues between the first cysteine of each disulfide bridge and the first cysteine of the next”. For example, for a sequence having Cys residues in positions 1, 5,10, and 14, knowledge that the disulphide bridge topology is connection of 1\_3 and 2\_4, immediately renders 8 and 7 as the numbers of residues between first and second pairs of cysteines, respectively, and 3, as the number of residues between the first cysteine of first disulfide bridge and the first cysteine of the second disulfide bridge. Thus, the disulphide bridge topology used in the referenced method is viewed as the disulfide signature addressed in the instant method (which is the same as claimed in instant claim 2).

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above, and that the above described referenced method and related computer implemented software applications directly anticipates the methods of detecting similarity between protein sequences comprising a plurality of disulfide signatures and domains as instantly claimed as well as the corresponding program and computer readable media.

Claims 5,6,8-12,14-16, 25-28, 30-32, 44,45,47-51,53,54 are rejected under 35 U.S.C.103(a) as unpatentable over Chuang et al, or Benham et al, or Mas et al.

With respect to claims 5,6,8-12,14-16, and corresponding claims 25-28, 30-32, and 44,45,47-51,53,54, if there are any differences between Applicant's claimed method and that of the prior art, the differences would appear minor in nature. Although the prior art do not teach all the aspects of using disulfide signatures as claimed, the nature of the problem to be solved – comparing protein sequences using disulfide connection characteristics - would lead inventors to look at references relating to computational methods of sequence comparison. Based on particular situation, it would be conventional and within the skill of the art to make decision to use of simplified, rather than full "signature" (as in claims 9,10) and/or to select or determine such result-oriented variables as parameters or criteria to be used as a measure of similarity of

“disulfide signatures” (as in claims 5,6,8), or appropriate criteria for clustering database sequences (as in claims 14-16), or, or associating disulfide signatures with other identifiers (as in claims 11,12)

***Conclusion.***

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./  
Primary Examiner, Art Unit 1631